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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,750	02/02/2001	Berend Jongsma	AHP-98248 P1	9381

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,750	JONGSMA ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- Th MAILING DATE of this communication appears on th cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The request filed on 2/28/02 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/775750 is acceptable and a RCE has been established. An action on the RCE follows.

Applicant has cancelled claims 17 and 20, amended claims 1, 13, 15, 18, 19, 21, and 22, and added new claims 23 and 24 in paper no. 12. Claims 1-16, 18, 19, 21-24 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, 16, 18, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 has been amended to recite, "consisting essentially of" rather than "comprising". It is unclear what steps are intended to be omitted from the process by the new claim language. This rejection also affects dependent claim 14.

Claim 16 states that the vaccine "does not significantly decrease" the percentage of hatchings. It is unclear what would be considered a "significant decrease".

Claim 18 is vague and indefinite because the metes and bounds of what is intended by "substantially no virus" is indeterminate.

Claim 24 is unclear because the claim refers to infectious bronchitis (IB). It is presumed that applicant is referring to IBV because the claim states that the IB in the vaccine is a strain,

but it is not clear whether this is the case. It is suggested that applicant maintain the terminology consistent with the other claims, i.e. "IBV" and "avirulent".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite, "not serially passaging said vaccine through tissue culture". This negative limitation appearing in amended claim 1 cannot be found in the original disclosure. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). This rejection also affects claims 2-12.

Claim 13 has been amended to recite, " consisting essentially of" in the process. There is no support in the specification for excluding steps that are encompassed by the original claim language, "comprising". Applicant has not pointed to support for this new claim language in the original specification and the Examiner is unable to find support for this language or concept in the disclosure. This rejection also affects claim 14.

Applicant argues that amended claim 1 explicitly states what is implicitly set forth throughout the specification and especially in example 1 on page 5 and 6 regarding the vaccine

not being passaged. Applicant also argues that the instant case is not similar to Purdue Pharma L.P. v. Faulding Inc., 230 F .3d 1320, 56 USPQ2d 1481, 1487 because it is clear that the disclosure conveys administering a commercial vaccine without further serial passaging to the skilled artisan.

Applicant's arguments have been considered, but are not found persuasive. Applicant's assertion that the instant disclosure would convey to a skilled artisan that the commercial vaccine composition is not subsequently passaged upon receipt is not supported. Niether the disclosure as a whole or example 1 cited for support by applicant indicate that any commercial vaccine obtained cannot be further serially passaged in order to practice the invention. There is support in the specification for using any commercially available IBV vaccine, which may include those derived by some means of attenuation by passaging to practice the claimed invention. On page 2, line 19 to page 3, line 1, the specification teaches that "[a]ll types of vaccines for inoculation are contemplated for use in the invention". This embodiment encompasses not only all commercially available vaccines, but also any non-commercially vaccine that has been attenuated by serial passage, as well as any vaccine that has been bought and passaged for further attenuation. Therefore, there is no support for applicant's assertion that the skilled artisan would "immediately discern the limitation at issue" because the issue is never discussed, conveyed or implied in the disclosure, and cannot be claimed. Further, the Office fully agrees that the specification is not required to provide *ipsis verbis* support, as long as the specification clearly conveys to those skilled in the art the specific subject matter instantly claimed. The instant disclosure does not suggest or imply that commercially obtained vaccines cannot be or are not

further serially passaged to practice the claimed invention and therefore, the new matter rejection is maintained.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-13 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakenell et al. for reasons of record.

New claim 23 is drawn to a the vaccine being commercially available. Wakenell et al. teaches that the IBV vaccine used is commercially available, see the first sentence of the abstract.

Applicant argues that Wakenell et al. does not anticipate the claims because the reference does not describe the dosage amounts in the instant claims and doe not describe a vaccine that has not been serially passaged.

Applicant's arguments are unpersuasive since the claims Wakenell et al. anticipates do not recite dosage amounts and because the added negative limitation of not serially passaging the vaccine is new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 14-16, 18, 19, 21, 22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakenell et al. as applied to claims 1, 7-13 and 16 above, and further in view of Sharma et al. for reasons of record.

Applicant again argues that Wakenell does not teach a vaccine that has not been serially passaged and seems to mandate passaging to effectively reduce pathogenicity. Applicant further suggests that Wakenell et al. felt that any further reduction in dosing would not have produced effective results because it still would have been too lethal and the reference does not provide teaching that the instant invention could be obtained.

Applicant's arguments have been fully considered, but are found unpersuasive. Applicant is arguing the limitation of no serial passage of the vaccine that is not supported by the specification. In addition, applicant's conjecture of how Wakenell et al. felt about a further reduction in dosage is moot. The Office disagrees that there is no suggestion in Wakenell et al. to further weaken the vaccine. Wakenell et al. explicitly teaches, "as the cell culture passage level increased, the pathogenicity of the virus for embryos decrease", see the next sentence after applicant's quoted citation in the first column on page 935 and Table 1. Therefore, Wakenell et al. clearly suggests the beneficial effects of a less virulent vaccine formulation. Therefore, the teachings of Wakenell et al. and Sharma et al. render the invention as a whole prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SAF
Shanon Foley/SAF
May 18, 2002

James C. Housel 5/20/02

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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